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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/524,819 | 02/18/2005 | Ulrich Kautz | 26588U | 1996 |

34375 7590 07/05/2006

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 10/524,819 | Applicant(s) KAUTZ ET AL. | |
| | Examiner Charanjit S. Aulakh | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13,15 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13,15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/27/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on April 7, 2006, the applicants have amended claims 2, 18 and 19.
2. Claims 1-13, 15 and 18-20 are pending in the application.

Response to Arguments

3. Applicant's arguments filed on April 7, 2006 have been fully considered but they are not persuasive regarding enablement rejections of claims 18 and 20. The applicants have amended claims to overcome indefiniteness rejections. In regard to enablement rejection of claims 18 and 20, the applicants have provided several references to support the enablement. Although the compounds in all these references are shown to inhibit PDE4 yet they are structurally very different from the instant compounds. The applicants have not provided any references for structurally closely related compounds to have well known utility for treating diseases such as allergic rhinitis, rheumatoid arthritis, dermatoses, ulcerative colitis and crohn's disease. On the other hand, several PDE4 inhibitors with diverse structures are currently in phase I, II and III clinical trials for treatment of asthma and/or COPD (see Dyke and Montana, Expert Opinion. Invest. Drugs, vol. 11, pages 1-13, 2002, specifically table 1 on page 2). Based on this information, the instant compounds will have utility for treating asthma and COPD but not all other diseases.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13, 15 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands*, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art and the breadth of claims.

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The instant claims are directed to solvates, hydrates, hydrate of a salt or salt of solvate of instant compounds of formula (I), pharmaceutical compositions containing them and methods of using them. However, the specification is not enabling for preparing solvates, hydrates, hydrate of a salt or salt of solvate of instant compounds of formula (I). The specification merely mentions on page 6, first paragraph that it is known to one skilled in the art that when the compounds of instant invention are isolated in crystalline form, can contain various amounts of solvents. However, there is no teaching in the specification regarding any particular crystalline form of instant compounds and any solvent used. There is no teaching or guidance in the specification for preparing any solvate or hydrate of instant compounds. There is not even a single example present in the specification for preparing any solvate or hydrate of instant compounds of formula (I) and their salts. There is no teaching or guidance in the specification regarding different crystalline forms or different hydrate forms of instant compounds of formula (I). The instant compounds of formula (I) encompasses hundreds of thousands of compounds based on the values of variables R1-R7 and R31 and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to prepare every possible solvate and hydrate form of instant compounds of formula (I) and their salts.

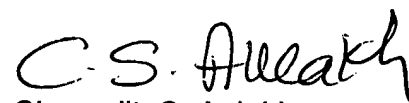
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

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(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charanjit S. Aulakh
Primary Examiner
Art Unit 1625